IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE BEXTRA AND CELEBREX)
MARKETING SALES PRACTICES AND) CIVIL CASE NO. 1:08-cv-402
PRODUCT LIABILITY LITIGATION)
)
) Related Case Number:
) M:05-cv-01699-CRB
) MDL No. 1699
) Pending in the Northern District of
) California, San Francisco Division

DECLARATION OF CATHERINE D. DEANGELIS, MD, MPH IN SUPPORT OF RESPONSE TO MOTION TO COMPEL PRODUCTION OF DOCUMENTS

Catherine D. DeAngelis, MD, MPH declares as follows:

- 1. My name is Catherine D. DeAngelis, MD, MPH.
- 2. I am a board-certified and licensed pediatrician. I have served as Vice Dean of Academic Affairs and Vice Dean of the Faculty of Johns Hopkins University School of Medicine, and continue as Professor on the faculty.
- 3. Presently, I am the Editor-in-Chief of The Journal of the American Medical Association ("JAMA"). I have held this position since 2000.
- 4. I am also Senior Vice President of Scientific Publications and Multimedia Applications for the American Medical Association ("AMA"), a position I have also held since 2000. As such, I am responsible for the AMA's peer-reviewed publications, including JAMA, the Archives of Internal Medicine ("AIM") and eight other Archives Journals published in print, foreign language, and web site formats.
- 5. In my capacity as the Editor-in-Chief of JAMA, I am ultimately responsible for making editorial policy, staffing and other decisions regarding the content of JAMA and the criteria for submission and publication of manuscripts. I am assisted by

talented team of editors, including the Editors of each Archives Journal, such as AIM, all of whom I select.

- 6. Before my current appointments, I served as Editor of the Archives of Pediatrics and Adolescent Medicine from 1994 to 2000.
- 7. I have personal knowledge of the matters stated in this Declaration and the facts as stated in the AMA's brief. I have read the brief and the facts stated in the brief and attest that they are true and accurate to the best of my personal knowledge. As to a few historic facts in both the AMA's brief and this Declaration, I am relying upon certain business records of the American Medical Association, in my capacity as Senior Vice President.
- 8. The American Medical Association, an Illinois not-for-profit corporation headquartered at 515 North State Street, Chicago, Illinois, is dedicated to the promotion of the science and art of medicine and the betterment of public health. Formed in 1847, the AMA currently is the largest association of physicians and medical students in the United States. The AMA played an instrumental role in the creation of many state and national medical societies with common interests. In 1847, the Illinois State Medical Society was organized at the behest of the AMA, and its delegates have shaped AMA policy since 1853. In 1951, the AMA was a charter member and organizer of The Joint Commission on Accreditation.
- 9. Physicians are elected to the AMA House of Delegates as representatives of state, county, and local medical societies and institutions and of medical colleges. The AMA works to advance principles of patient advocacy, ethics, education, professionalism, standard setting, and quality of patient care.

- 10. The AMA has been instrumental in improving patient healthcare through public policy initiatives now considered the bedrocks of public health. For example,

 AMA resolutions led to the requirement that all automobiles be equipped with safety belts; that alcoholism be treated as a illness; and that tobacco companies disclose the risk of cancer, heart attack, stroke and fetal injury from tobacco use. In 1982, the AMA encouraged each state medical society to seek and support legislation to raise the legal drinking age to 21, with the aim of reducing alcohol related injuries and deaths.
 - 11. JAMA and AIM are published in Chicago, Illinois, by the AMA. JAMA is the mostly widely circulated general medical journal in the world, with more than 350,000 subscribers. English language copies of JAMA are distributed in 132 countries, and JAMA is reprinted in eight languages. JAMA has been published continuously for 124 years, and AIM itself has been published for one hundred years. AIM is the oldest and largest of nine specialty medical journals in the JAMA family of Archives Journals.
 - 12. JAMA is a general medical journal that publishes scientific articles, commentaries, and news involving all fields of medicine, including medical research, significant clinical observations, diagnostic and therapeutic developments, legal and social matters of interest to physicians, and issues of medical ethics. AIM, with a print circulation of 87,000, primarily appeals to physicians who specialize in Internal Medicine, Family Medicine, and General Medicine.
 - 13. JAMA's motto, "To promote the science and art of medicine and the betterment of the public health," is published in every one of its 48 issues annually. We strive to provide physicians with the most reliable medical research and information, including studies of morbidity and mortality, to help them diagnose and treat their

patients and also to encourage additional research, discussion, and evidence-based medicine to improve patient care.

- 14. AIM has a similar mission: "To promote the art and science of medicine and the betterment of human health by publishing manuscripts of interest and relevance to internists practicing as generalists or as medical subspecialties." When created by the AMA in 1908, its charge was to "bridge the gulf between purely scientific research and its application to practical clinical medicine."
- 15. The readers of JAMA and AIM are predominately physicians, medical school faculty, and investigators medical scientists conducting original research for a variety of sponsors. Because of this specialized audience, we work to make the medical information we communicate as accurate as possible. To implement this goal, our journal editors rely on rigorous peer review to evaluate the methodology, statistical analysis, and overall medical accuracy of manuscripts submitted for publication.
- 16. The vast majority of manuscripts submitted to JAMA are rejected. In a typical year, only seven or eight percent of more than 5,000 manuscripts are selected for publication. Some papers submitted to JAMA are referred to AIM, as a better potential fit for the readers of that journal. AIM is competitive and selective as well, publishing less than twenty percent of the manuscripts submitted.
- 17. All manuscripts published in JAMA and AIM are subjected to peer review.
- 18. In the peer review process, a committee of individuals with expertise in the subject matter of an article review the soundness of the article's methodology, data,

and conclusions. The editors of JAMA and AIM decide which registered peer reviewers should be consulted on particular manuscripts.

- 19. Both JAMA and AIM guarantee the confidentiality of their peer reviewers and other individuals who may provide information to these journals in the course of the editorial process.
- 20. When contacted, peer reviewers are reminded of the confidentiality surrounding the following: the invitation to serve as a peer reviewer, the contents of the manuscript, the scope of the assignment, and the entire process.
- 21. Peer reviewers are urged to make frank and candid comments regarding the clarity, structure and conclusions of the paper, as well as its contribution to the medical literature and gravitas. Peer reviewers may tender suggestions that a manuscript be revised in an effort to make it better suited for publication in JAMA or AIM. JAMA and AIM editors review the manuscripts and consider the recommendations, comments, and suggested revisions. Even after revision, some manuscripts are rejected by the editors of JAMA and AIM, at which point the authors are free to submit the paper to another journal for consideration.
- 22. JAMA has made a commitment to abide by the strict standards of confidentiality adopted by the International Committee of Medical Journal Editors. These standards admonish editors and reviewers not to disclose information about manuscripts, including their receipt, their content, their status in the reviewing process, their criticism by reviewers, or their ultimate fate. I am one of the eleven editors who comprise this International Committee.

- 23. I have authored or edited 11 books and over 200 original articles, chapters, editorials and abstracts. I have been a peer reviewer for some of the most prestigious medical journals in the world, and interact with peer reviewers virtually every working day. Peer reviewers are more candid with me, and I with them, because we rely on the confidential nature of our communications as we vet manuscripts under consideration.
- 24. While some statistical reviewers are offered a small honorarium, manuscript peer-reviewers themselves are not compensated. These individuals give their time and talent to learn, grow, and expand their professional reach and experience, by contributing to advances in medical science, patient care, and public health.
- 25. The candor and trust essential to the peer review process, and its association with the production of top-quality medical literature, would be threatened if these confidential assessments were released into the public domain. The individuals who donate their time to the peer-review process did not agree to become the subjects of depositions, subpoenas, or public debate among litigants in lawsuits over what they believed to be confidential comments made to me and my team of manuscript editors.
- 26. I am concerned that if this motion is granted, subpoenas of this type may become standard practice, with the inevitable result being a severe decline in medical reviewers willing to accept additional requests to participate in peer review.
- 27. At JAMA and AIM, we strive to gather, edit and publish the best evidence-based medicine possible. We have a special interest in clinical trials and original research that suggest a reduction in morbidity (the prevalence or incidence of a disease, condition or state) and mortality (the proportion of deaths to population). Since these trials involve human participants and patients, usually with a disease, risk factors

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for a disease, or both, editors must closely scrutinize the efficacy and effectiveness of

drugs and treatment regimes, allowing for the normal results of a disease, or the effect of

external influences, such as a drug, ultimately reporting the benefit or risk to patients

(ideally while a trial is still underway). The confidential peer review process is a critical

yet fragile component of this goal.

28. Physicians, and thus their patients, depend upon what we publish. If a

promising drug appears to have an adverse side effect, that fact needs to be considered,

discussed and reported, with supporting data so physicians can be informed, and make

intelligent prescribing decisions. Some early clinical trials are affirmed or called into

question by later research. Science and medical research evolve, and new or broader data

may prompt some peer reviewers and editors to change their minds. These individuals

require the freedom to make these decisions in confidence.

29. Without candid and thorough peer review from the best medical minds,

AMA's journals cannot properly discharge their mission to advance the betterment of

public health.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: February 29, 2008

Catherine D. DeAngelis, MD, MPH

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